

DEC 03 2001

**MicroMark™ II Tissue Marker**  
**510(k) Summary of Safety and Effectiveness Information**

**Company**

Ethicon Endo-Surgery, Inc.  
4545 Creek Road  
Cincinnati, OH 45242

K013413

**Contact**

Georgia C. Abernathy, MBA, RAC  
Senior Regulatory Affairs Associate  
Telephone: (513) 337-3179  
Fax: (513) 337-3773  
Email: gabernat@eesus.jnj.com

**Date Prepared**

October 12, 2001

**Device Name**

Trade Name: MicroMark™ II Tissue Marker  
Classification Name: Implantable Staple

**Predicate Device**

MicroMark™ Clip

**Device Description**

The MicroMark II Tissue Marker is a sterile, single patient use device comprised of a small stainless steel marker (clip) and a disposable introducer and applier. The introducer consists of a flexible tube, a distal ramp, and a lateral port. The applier consists of a flexible shaft, a deployment mechanism and a handle. The marker is located at the distal end of the applier.

The MicroMark II Tissue Marker is used with the currently marketed Ethicon Endo-Surgery MAMMOTOME® Probes which function as standard rigid coaxial introducer needles post biopsy.

The Tissue Marker is used with imaging guidance (stereotactic and ultrasound). The stainless steel marker is Magnetic Resonance (MR) safe at 3.0 Tesla field strength or less. The marker, when present in a patient undergoing an MRI procedure at 3.0 Tesla or less, will not create an additional hazard or risk with respect to magnetic field-related interactions, movement / dislodgment, or heating.

**Indications for Use**

The MicroMark II Tissue Marker is indicated for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.

**Technological Characteristics**

No design changes have been made to the MicroMark II Tissue Marker. The specification and labeling-modified marker is identical and possesses the same technological characteristics as the currently marketed marker.

**Performance Data**

Bench testing was performed to demonstrate that the device will perform as intended in MRI procedures utilizing 3.0 Tesla or less.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Georgia C. Abernathy, MBA, RAC  
Senior Regulatory Affairs Associate  
Ethicon Endo-Surgery, Inc.  
4545 Creek Road  
Cincinnati, Ohio 45242-2839

DEC 03 2001

Re: K013413

Trade/Device Name: MicroMark™ II Tissue Marker  
Regulation Number: 21 CFR 878.4300  
Regulation Name: Implantable Clip  
Regulatory Class: Class II  
Product Code: NEU  
Dated: October 12, 2001  
Received: October 15, 2001

Dear Ms. Abernathy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510 (k) Number (if known): K013413

Device Name: MicroMark™ II Tissue Marker

### Indications for Use:

The MicroMark™ II Tissue Marker is indicated for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)